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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,140	12/12/2003	Stanley B. Prusiner	UCAL-131CON3	5681

24353 7590 10/06/2006

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EXAMINER	
LEVY, NEIL S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,140	PRUSINER ET AL.	
	Examiner	Art Unit	
	NEIL LEVY	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings are acceptable, but do not present clearly , as photographs might.

Due to the large number of references submitted on the IDS's, all references have been considered in manner as references encountered during a normal office search. Applicant's are requested to point out references pertinent to the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for contacting with SDS and acid at 37-140 degrees centigrade, does not reasonably provide enablement for Identification of non-infectious prions

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. No means are claimed to provide the practitioner with knowledge that prions are present, and then made non-infectious. Lack of infection in a limited number of animals does not validate non-infectivity. See example Deslys showing isolation of prions in SDS, example 2.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 38 U. S. C. 112, the first paragraph have been described inn re Wands, 8 USPQ2D 1400 (Fed Cir. 1988). Among these factors are (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims. (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed,

it is the examiner's position that instant disclosure fails to meet the enablement requirement for the following reasons:

(1) The nature of the invention: claims are to unqualified non-infectivity
(2) The state of the prior art shows the use of these compounds for specific prion denaturation.
(3) The relative skill of those in the art. The relative skill of those in the art is high.
(4) The predictability or unpredictability of the art. The unpredictability of the art is very high.
(5) The breadth of the claims. The claims are very broad, as disruption can not be proven to have eliminated infectivity, even if the condition treated is not evidenced.
(6) The amount of direction or guidance presented. specific effects are limited to laboratory small scale data; the results expected are presumptive, no guidance given for subjecting feed to sufficient amount of contact with the claimed components & conditions, to ensure non-infectivity
(7) The presence or absence or working examples. There are none showing infectivity can not occur.
(8) The quantity of experimentation necessary extensive-there is no known levels of amount useful for ensuring the prion agent is non-infective.

Claim Rejections - 35 USC § 103

Double Patenting

Claims 39-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1of U.S. Patent No. 6719988 . Although the conflicting claims are not identical, they are not patentably distinct from each other because The patent provides non-infectious PrP with the instant acids, temperature SDS, pH, and would be known by the artisan to be applied to meat used as feed, but does not exactly recite instant claims.

Claim 39- 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1 of U.S. Patent No. 6, 720,355. Although the conflicting claims are not identical, they are not patentably distinct from each other because The patent meets the instant claims.

Claims 39-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim39-43, 45, 47, 51-53 are of copending Application No. 10/641687.
Although the conflicting claims are not identical, they are not patentably distinct from each other because, prions would be made non-infectious by contacting with alkyl sulfate , alcohol and acid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NEIL LEVY
Primary Examiner
Art Unit 1615

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